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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,271	08/22/2003	Jay D. Caplan	0010.0006	9460
29127	7590	02/21/2008		
HOUSTON ELISEEVA 4 MILITIA DRIVE, SUITE 4 LEXINGTON, MA 02421			EXAMINER ROZANSKI, MICHAEL T	
			ART UNIT	PAPER NUMBER
			3768	
			MAIL DATE	DELIVERY MODE
			02/21/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/646,271	<b>Applicant(s)</b> CAPLAN ET AL.	
	<b>Examiner</b> Michael Rozanski	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 29-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 29-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION*****Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-27 and 29-64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-73 of copending Application No. 10/426,750 in view of Auer et al (US 5,383,467).

Copending Application ‘750 claims features of the current invention including a method for analyzing blood vessels in the presence of intervening fluid comprising irradiating vessel walls with an optical source, collecting spectral

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responses, determining spectral responses of the vessel walls from the collected responses, and generating information for the assessment of vessel walls (i.e. diagnosis) in response to the determined spectral response of vessel walls. The spectral response of blood samples may be taken from the patient and may, subsequently, be compared to known spectral features of blood. Furthermore, the method includes analysis of the signal comprising algebraic analysis and chemometric analysis. '750 do not claim using optical signals to determine the mechanical relationship between the probe and the vessel. In the same field of endeavor, Auer et al teach of a determination of such a mechanical relationship (col. 4, lines 41-61). It would have been obvious to one with ordinary skill in the art at the time the invention was made to incorporate this teaching in order to alleviate the problem of not knowing the probe position in relation to the vessel wall.

This is a provisional obviousness-type double patenting rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-27 and 29-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Auer et al** (US 5,383,467) in view of **Narciso, Jr.** (US 5,217,456).

**Claims 1-27 and 29-64:** Auer et al disclose an optical catheter 15, and the use of an interferometer for analysis (col. 1, lines 6-11). At the distal end 27 of catheter 15, a coil is formed that has an outer diameter of 0.014 inches and a lens 58 are present, and could function as fins of the main catheter body (col. 5, lines 27-49). The catheter is positioned within a blood vessel 26, which is illuminated by a light source capable of operating at several wavelength simultaneously (col. 5, lines 9-14), wherein a beam of reflected energy is returned from tissue mass 28 by operation of catheter and fiber coupler 18 (col. 4, lines 41-43). Signal data from the photodetector 31 and signal detector 24 provides input to the computer 21, which includes a display output 35 whereat the X-Y plane configuration of vessel 26 is displayed and a determination of when the probe is close enough to vessel wall may be made (col. 4, lines 41-61). The amplitude of the interference signal is plotted as the Y coordinate, wherein a threshold could be set at a specific amplitude, and as a variable function of the X position of the catheter's distal end 27 within the vessel (col. 4, lines 41-61). The spikes in the signal plot represent discontinuities in the tissue mass 28 and the average slope of the signal plot between adjacent spikes represent the average extinction coefficient for the tissue mass (col. 4, lines 62-68). Thus, Auer et al disclose determining a mechanical relationship between the probe and the vessel

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walls, wherein the distance relationship provides an assessment of the vessel walls.

However, Auer et al do not disclose triggering an assessment of the vessel walls when a mechanical relationship has been determined or initiating diagnosis or treatment of the vessel walls in response to analyzing the optical signals indicative of a spectral response if the probe is determined to be close enough to the vessel walls to enable the diagnosis or treatment. In the same field of endeavor, Narciso, Jr. teach of an intravascular optical radial imaging system where scattered light interacts with tissue and various wavelengths of fluorescence light return to the catheter. The return signal enters a spectral analyzer where it is separated into various wavelengths, which indicate the composition of the vessel (col.I 2, lines 37-68). The spectral analyzer is used to determine where plaque is present in a blood vessel, which also indicates a narrowing of the vessel. Thus, Narciso, Jr. teaches receiving optical signals from vessel walls through intervening blood, analyzing the signals to determine whether plaque (and subsequently whether the vessel is narrowing and the probe is closer to the vessel wall, and using the signals to diagnose the vessel walls as healthy or unhealthy.

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have incorporated the teachings of Narciso, Jr. in order to alleviate the problem of not knowing the probe position in relation to the vessel wall while improving diagnosis or treatment of vessel wall.

***Response to Arguments***

Applicant's deferment with respect to the double patenting rejection is acknowledged and, therefore, currently maintained. Applicant's arguments filed 11/23/07 have been fully considered but they are not persuasive. Applicant argues that there is no teaching in Narciso to determine or assess probe head-blood vessel wall distance using the optical signals or trigger analysis based on such distance. However, Examiner finds that Narciso teaches of an intravascular optical radial imaging (IVORI) system that supplies both topographical and subintimal radial information that can be displayed as a cross-sectional view or as a 3-dimensional reconstruction of the vessel (col 2, lines 19-34). The cross-sectional view or 3-dimensional reconstruction of the inner walls of the vessel which is from the received optical signals and permits the operator to determine whether the probe is close enough to the vessel walls to enable assessment of the vessel wall (i.e. an image showing stenosis, or a narrowing of the blood vessel, allows the operator to make a determination that the probe is closer to the walls of the blood vessel to enable assessment of the vessel wall). The assessment of the vessel wall is a determination of the amount of atheromatous plaque built up, wherein information about the assessment is gained from the image showing stenosis and the different spectral wavelengths between plaque and healthy tissue. Contrary to Applicant's assertions, Narciso teach teaches receiving optical signals from vessel walls through intervening blood, analyzing the signals to determine whether plaque (and subsequently whether the vessel is

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narrowing and the probe is closer to the vessel wall, and using the signals to diagnose the vessel walls as healthy or unhealthy and thus the combination teaches all of the claimed features. As such, the rejection is proper and is hereby maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax



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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/  
Primary Examiner, Art Unit 3768

MR